DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

May 21, 2002

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 02-48

Katharine M. Cissna, Partner
The Best Fish Company, LLC
dba Crab Fresh
2130 Harbor Avenue Southwest
Seattle, Washington 98126

WARNING LETTER

Dear Ms. Cissna:

We inspected your firm located at 2130 Harbor Avenue Southwest, Seattle, Washington, on January 29, 30, and February 1, 2002, and found you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy-enclosed) listing the deviations was presented to you at the conclusion of the inspection. These deviations cause your whole-cooked crab distributed in wet-lock cartons with ice, and your refrigerated cooked crabmeat packed in vacuum-pulled metal cans, to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations are as follows:

1. You must conduct, or have conducted for you, a hazard analysis to determine the food safety hazards that are reasonably likely to occur for your fish products to comply with 21 CFR 123.6(a), and have a HACCP plan that addresses those food safety hazards to comply with 21 CFR 123.6(b). You do not have a HACCP plan that lists the food safety hazards that are reasonably likely to occur for your cooked crabmeat packed in vacuum-pulled metal cans to address the hazard of *Clostridium botulinum*. FDA believes that *Clostridium botulinum* is a hazard that is reasonably likely to occur in this product. For more information, we recommend chapter 13 in the Fish & Fisheries Product Hazards & Controls Guidance, Third Edition, June 2001.

2. You must have a HACCP plan that lists the critical limits that must be met at each critical control point, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for Whole Cooked Dungeness Crab does not list critical limits at the Cooling or Storage critical control points that are sufficient to control pathogen growth. Significant pathogen growth and toxin formation can occur at temperatures above 70 degrees F. Your Cooling critical control point should include the temperature critical limit of 70 degrees F and a safe time period to reach that temperature based on the growth potential of your target pathogen. If *Staphylococcus aureus* were the target pathogen, two hours would be the recommended safe time critical limit.

   Your firm also stores crabs in shipping containers with ice and your records indicate that you periodically ship crabs in ice when they have attained an internal temperature between 70 degrees F and 50 degrees F. Consequently, your critical control points for Cooling and Storage must also include a critical limit that assures the crabs continue cooling to 40 degrees F under these conditions. Since your crabs are stored and shipped in ice, an appropriate critical limit would be to assure that the ice is adequate (i.e., the ice should completely surround the crabs not just on top of the packed crabs).

3. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the Cook critical control point to control pathogen survival listed in your HACCP plan for Whole Cooked Dungeness Crabs. Your plan states that you will record observations for cook time and temperature for "every cook." You have stated, and the records reviewed by our investigator, show that you only record the values for the first cook batch of the day.

4. You must have a HACCP plan that lists monitoring procedures for each critical control point to ensure compliance with critical limits, to comply with 21 CFR 123.6(c)(4).

   - Your firm's HACCP plan for Whole Cooked Dungeness Crabs lists the monitoring procedure "Take internal temperature of crab" at the Cooling critical control point that is not adequate to control pathogen growth. The critical limit listed at this critical control point, "Exposure to temp. over 40 F does not exceed 4 hrs", cannot be monitored by taking the internal temperature of the crab. Your critical limit lists an ambient temperature, not the product internal temperature.

   - Your firm's HACCP plan for Whole Cooked Dungeness Crab list the monitoring frequency "Every 12 hrs. when product is being stored" at the Storage critical control point that is not adequate to control pathogen growth. Only continuous temperature monitoring or an equivalent method can assure that storage temperatures are consistently maintained at safe levels 24 hours for cooked

ready-to-eat products a day. Temperature checks at 12-hour intervals allow the potential of elevated temperatures and pathogen growth for significant periods of time. Examples of appropriate methods include temperature-recording devices, a 24-hour high temperature alarm for the cooler, or, when your products are stored in ice, monitoring the adequacy of the ice twice a day. In addition, monitoring the temperature every twelve hours cannot assure that the time critical limit of four hours is not exceeded.

5. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). Your firm did not monitor the following areas with sufficient frequency:

   - Safety of the water in that an inadequate back flow prevention device was observed on the pipe used to fill the crab cooling tanks.
   - Prevention of cross contamination in that condensation was observed on the ceiling and exposed insulation was observed to hang from the ceiling throughout the facility.
   - Exclusion of pests in that louvered fans are open to the outside of the facility.

Importer Deviations

6. You must have product specifications that are designed to ensure that the fish and fishery products you import are not adulterated under section 402 of the Act because they may be injurious to health or have been processed under insanitary conditions, to comply with 21 CFR 123.12 (a)(2)(i). However, your firm does not have product specifications for live Dungeness crabs imported from Canada.

7. You must implement an affirmative step that ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for live Dungeness crabs manufactured by [redacted]

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct this deviation. You may wish to include in your response documentation such as your revised HACCP plan, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. Althar at (425) 483-4940.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483
21 CFR PART 123
Sections 402 and 801(e) of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with disclosure statement